

§ 93.318

records and evidence, to perform forensic or other analyses or as otherwise needed to conduct an HHS inquiry or investigation or for ORI to conduct its review or to present evidence in any proceeding under subparts D and E of this part.

§ 93.318 Notifying ORI of special circumstances.

At any time during a research misconduct proceeding, as defined in § 93.223, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

- (a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- (b) HHS resources or interests are threatened.
- (c) Research activities should be suspended.
- (d) There is reasonable indication of possible violations of civil or criminal law.
- (e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- (f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- (g) The research community or public should be informed.

§ 93.319 Institutional standards.

(a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research misconduct.

(b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution's internal standards of conduct.

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Subpart D—Responsibilities of the U.S. Department of Health and Human Services

GENERAL INFORMATION

§ 93.400 General statement of ORI authority.

(a) *ORI review.* ORI may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter. The ORI response may include, but is not limited to—

- (1) Conducting allegation assessments;
- (2) Determining independently if jurisdiction exists under this part in any matter;
- (3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;
- (4) Recommending that HHS should perform an inquiry or investigation or issue findings and taking all appropriate actions in response to the inquiry, investigation, or findings;
- (5) Notifying or requesting assistance and information from PHS funding components or other affected Federal and state offices and agencies or institutions;
- (6) Reviewing an institution's findings and process;
- (7) Making a finding of research misconduct; and
- (8) Proposing administrative actions to HHS.

(b) *Requests for information.* ORI may request clarification or additional information, documentation, research records, or evidence from an institution or its members or other persons or sources to carry out ORI's review.

(c) *HHS administrative actions.* (1) In response to a research misconduct proceeding, ORI may propose administrative actions against any person to the HHS and, upon HHS approval and final action in accordance with this part, implement the actions.

(2) ORI may propose to the HHS debarbing official that a person be suspended or debarred from receiving Federal funds and may propose to other appropriate PHS components the implementation of HHS administrative

actions within the components' authorities.

(d) *ORI assistance to institutions.* At any time, ORI may provide information, technical assistance, and procedural advice to institutional officials as needed regarding an institution's participation in research misconduct proceedings.

(e) *Review of institutional assurances.* ORI may review institutional assurances and policies and procedures for compliance with this part.

(f) *Institutional compliance.* ORI may make findings and impose HHS administrative actions related to an institution's compliance with this part and with its policies and procedures, including an institution's participation in research misconduct proceedings.

§ 93.401 Interaction with other offices and interim actions.

(a) ORI may notify and consult with other offices at any time if it has reason to believe that a research misconduct proceeding may involve that office. If ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the Department of Justice (DOJ), the HHS Inspector General (OIG), or other appropriate investigative body. ORI may provide expertise and assistance to the DOJ, OIG, PHS offices, other Federal offices, and state or local offices involved in investigating or otherwise pursuing research misconduct allegations or related matters.

(b) ORI may notify affected PHS offices and funding components at any time to permit them to make appropriate interim responses to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, and to conserve public funds.

(c) The information provided will not be disclosed as part of the peer review and advisory committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.

RESEARCH MISCONDUCT ISSUES

§ 93.402 ORI allegation assessments.

(a) When ORI receives an allegation of research misconduct directly or becomes aware of an allegation or apparent instance of research misconduct, it may conduct an initial assessment or refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.

(b) If ORI conducts an assessment, it considers whether the allegation of research misconduct appears to fall within the definition of research misconduct, appears to involve PHS supported biomedical or behavior research, research training or activities related to that research or research training, as provided in § 93.102, and whether it is sufficiently specific so that potential evidence may be identified and sufficiently substantive to warrant an inquiry. ORI may review all readily accessible, relevant information related to the allegation.

(c) If ORI decides that an inquiry is warranted, it forwards the matter to the appropriate institution or HHS component.

(d) If ORI decides that an inquiry is not warranted it will close the case and forward the allegation in accordance with paragraph(e) of this section.

(e) ORI may forward allegations that do not fall within the jurisdiction of this part to the appropriate HHS component, Federal or State agency, institution, or other appropriate entity.

§ 93.403 ORI review of research misconduct proceedings.

ORI may conduct reviews of research misconduct proceedings. In conducting its review, ORI may—

(a) Determine whether there is HHS jurisdiction under this part;

(b) Consider any reports, institutional findings, research records, and evidence;

(c) Determine if the institution conducted the proceedings in a timely and fair manner in accordance with this part with sufficient thoroughness, objectivity, and competence to support the conclusions;